therapeutic sexual dysfunction treatment effect on the administration of the vasoactive, cGMP-PDE inhibiting compounds herein.

The rejection is traversed on the basis that the double patenting reference (08/549,792, hereinafter "the reference") alone provides no basis for it. The process leading to an erection involves sexual stimulation. The nervous system plays a significant part in this overall process. Impairment of the nervous system, as through nerve damage arising from, for example, surgery or a pelvic injury (see Applicants' specification at page 1, lines 23-25) can cause or be associated with sexual dysfunction. The reference contains no suggestion which would cause one of ordinary skill in the art to believe that a male with an injured spinal cord (i.e., an impaired nervous system) would be able to achieve an erection. It discloses the genus of specific compounds useful in the invention, but says nothing about whether the compounds would be useful in treating patients with an injured spinal cord.

Beyond not mentioning the treatment of sexual dysfunction in people with an injured spinal cord, the double patenting reference provides no expectation of success, and the law is emphatic that the prior art must not only provide a suggestion to do what the inventor has done, it must also provide a reasonable expectation of success. The Federal Circuit has explained the proper test:

> The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out **and would have a reasonable likelihood of success**, viewed in light of the prior art. **Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure** (emphasis added).

In re Dow Chemical Co., 5 USPQ.2d 1529, 1531 (Fed. Cir. 1988); Amgen, Inc. V. Chugai Pharmaceutical Co. Ltd. 18 USPQ.2d 1016. 1022-23 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991).

Clearly, the double patenting reference provides no such suggestion. The Examiner has provided no basis as to why one of ordinary skill in the art would be justified in concluding, before the fact, that a cGMP PDE_V inhibitor would be

effective in the treatment of spinal cord injury. Only Applicants have disclosed that teaching, and that which only the inventors taught may not be attributed to the prior art. W. L. Gore & Associates, Inc. v. Garlock, Inc., 220 USPQ 303 (CAFC 1983).

It is respectfully requested that the double patenting rejection be withdrawn.

Claims 1, 2, 5 and 9-10 stand rejected under 35 USC 102(a), and claims 1-2 and 5-10 stand rejected under 35 USC 103(a) over Derry et al., Neurology, 1997, Vol. 48, No. 3, page A215.

Applicants herewith submit the Declaration under 37 CFR 1.131 of Murray C. Maytom, one of the inventors in this application. Dr. Maytom has provided, as Exhibit A to the Declaration, a copy of a protocol for a clinical study, which study was initiated and completed prior to the Derry article publication date of March, 1997. For completeness, the dates noted in the protocol have been removed by lining through with a black magic marker. It was the foregoing study which provided the data for the Derry Abstract, as can be seen by comparing the "Results" section of Derry with Paragraph 6 of the Declaration, in which Dr. Maytom offers the results from the clinical trial. The Declaration additionally states that the clinical trial was initiated and completed prior to the Derry Abstract. Clearly, then, the Declaration supports that the invention - - treating erectile dysfunction in patients with spinal cord injury - - was actually reduced to practice prior to Derry. The Declaration accordingly provides dispositive evidence supporting that the invention was made prior to Derry et al.

Thus Derry has been removed as a reference against this application, and it is respectfully requested that both the §102 and §103 rejections based on Derry be withdrawn.

Claims 1, 2, and 5-10 stand rejected under 35 USC 103(a) as being unpatentable over WO 94/28902 in view of Doherty. It is noted that, on its face, Doherty has an earliest apparent effective filing date of October 28, 1997. With reference to the discussion above and the antedating of Derry by means of Applicants' Rule 131 Declaration, it is noted that the Rule 131 Declaration also removes Doherty as a reference. That is, by antedating the March, 1997 publication date of Derry, the Rule 131 Declaration also antedates the October 28, 1997 filing date of Doherty. For this reason alone, the §103 rejection over WO 94/28902 in view

of Doherty should be withdrawn. Even though WO 94/28902 remains as a reference, it is respectfully submitted that the instant invention is patentable thereover. The treatment of erectile dysfunction in patients with spinal cord injury is not suggested in WO 94/28902. As noted above, for an invention to be obvious over the prior art, the prior art must somehow suggest the invention. The prior art must also provide an expectation of success. It is submitted that these requisite elements - - the suggestion and the expectation of success - - are absent from the prior art in the instant case. In re Dow Chemical Co., supra.

In view of the foregoing comments and the Rule 131 Declaration submitted herewith, this case is believed to be in condition for allowance, and a Notice of Allowance is courteously solicited.

Respectfully submitted,

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